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No. 04-476

SUPREME COURT, U.S.
FILED
NOV 8 - 2004
OFFICE OF THE CLERK

In The Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC., MONSANTO CO., PHARMACIA CORPORATION, AND PFIZER, INC.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR PETITIONER

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November 8, 2004

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REPLY BRIEF FOR PETITIONER

A. The Instant Case Is An Ideal Vehicle For Resolution Of The Extremely Important Question Presented

Respondents are wrong that this case involves a "hypothetical" or "purely academic" issue. Br. in Opp. 1-2, 12, 16 (citations omitted). There is nothing academic or hypothetical about the Federal Circuit's invalidation of petitioner's patent for failure to meet that court's judicially-fashioned separate written description requirement. That is the sole ground on which the court of appeals ruled.

1. There are not "multiple alternative grounds" for the decision below, as respondents claim. *See* Br. in Opp. 1, 2, 16-18. The Federal Circuit did not hold that the patent failed to meet the enablement requirement. Indeed, it expressly declined to address that issue. Pet. App. 28a ("In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.").

Moreover, respondents ignore the fact that this case comes to the Court from a grant of summary judgment. In addition to relying on the patent's statutory presumption of validity under 35 U.S.C. § 282, petitioner submitted expert evidence that its patent does indeed enable one skilled in the art to make and use the invention. (1) Professor Schofield averred that those skilled in the art "would have been able to practice the inventions of the '850 patent with respect to the discovery of therapeutically useful COX 2 selective inhibitors on the basis of the disclosures of the . . . application together with their skill in the art" and "could have practiced the inventions . . . without undue experimentation." Fed. Cir. J. App. A1208. (2) Professor McGiff directly addressed respondents' objection that there was no specific compound identified, explaining that "it would not be necessary for one of ordinary skill in the art to know the structure of a compound before screening it to determine whether it was suitable for use in the claimed method." *Id.* at A344. (3) Indeed, Dr. Suto averred, without contradiction, that "a

major reason why [respondents'] selective Cox-2 inhibitor program succeeded so quickly [in making a compound] was because of the detailed knowledge available about the Cox-2 target (which information was set out in the [petitioner's] September 1992 [patent] application)." *Id.* at A1278.

Respondents did not introduce *any* contrary evidence of what one skilled in the art could or could not make or use based on the patent. Because the enablement standard requires the perspective of one skilled in the art, petitioner's unrefuted evidence, especially considered in light of the burden on respondents to overcome the statutory presumption of validity by clear and convincing evidence, *see* Pet. 22-23, means that whether the patent meets the enablement standard (which it does) is a question that cannot be resolved adversely to petitioner on summary judgment. Pet. C.A. Br. 29-35. The trial court's ruling to the contrary was error that the Federal Circuit did not reach because it based its decision on the failure to meet its separate written description requirement. *See* Pet. App. 28a.

The passing comment in the course of a discussion of a "hypothetical policy analysis" by one of the dissents from denial of rehearing *en banc*, to the effect that petitioner's invention was not enabled, cannot substitute for evidence in the record of the opinion of one skilled in the art, as respondents would have it. Br. in Opp. 9, 12, 17. And the panel's citation to the skilled-in-the-art requirement (Br. in Opp. 21) likewise does not alter the fact that the record contains no evidence that those skilled in the art could not make and use the invention based on the patent. Although the panel may have suggested that it was applying the perspective of one skilled in the art, it could not have applied such a perspective that was contrary to the uncontroverted skilled-in-the-art evidence of record and the presumed validity of the patent.

2. Petitioner's patent did not fail to satisfy the requirements of 35 U.S.C. § 102(f). Respondents' reference (Br. in Opp. 1, 9, 17) to dicta in a final footnote of the opinion below suggests that Section 102(f) prevents patents for inventions such as petitioner's that constitute

methods or processes. But Section 102(f) provides only that an applicant is not entitled to a patent if the applicant "did not himself invent the subject matter sought to be patented," thereby simply ensuring that an applicant does not seek to patent the invention of another inventor. 35 U.S.C. § 102(f); *see OddzOn Prods. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997).

The Patent Act addresses the issue of what constitutes a patentable invention not in Section 102(f) but in Section 101, which authorizes an individual who "invents or discovers any new and useful process, [including an art or method,] machine, manufacture, or composition of matter," including "a new use of a known process, machine, manufacture, composition of matter, or material" to obtain a patent. 35 U.S.C. §§ 101, 100(b) (defining "process"). Plainly, petitioner's discovery of Cox-2 and its invention of a new method of treating pain (described by respondents' chief medicinal chemist as the "holy grail in this area," Fed. Cir. J. App. A760) fall squarely within the Act's scope under Section 101.

In any event, respondents never raised an argument regarding Section 102(f) in either the district court or the Federal Circuit, suggesting that they, too, recognized the paucity of the argument. Because the issue was not raised or passed on below, respondents should not now be allowed to invoke it to prevent review of the wide-reaching and erroneous ruling below.

3. a. Respondents suggest (Br. in Opp. 9, 12-13) that there is little practical significance to whether there is a written description requirement untethered to enablement. They cite one of the dissents from denial of rehearing *en banc* for the proposition that "the application of this independent written description requirement has never made, and is unlikely to make, a difference in the outcome of any case." Br. in Opp. 2; *id.* at 1, 9, 12. That is a strange argument – that for 30 years, and amidst great controversy, the Federal Circuit has been engaged in a meaningless exercise of attempting to create a separate written description requirement, and a pointless internal debate about whether there is any statutory support for such a

requirement, because whatever the result, it does not make any difference. In fact, the reality is to the contrary.

In the nearly contemporaneous opinion in *Chiron Corp. v. Genentech, Inc.*, a panel of the Federal Circuit, including some of the dissenters below, held that the patent application in that case met the enablement requirement of Section 112, but did not meet the Federal Circuit's separate written description requirement. *See* 363 F.3d 1247 (Fed. Cir. 2004), *petition for cert. pending*, No. 04-477. *See also In re Curtis*, 354 F.3d 1347, 1357 (Fed. Cir. 2004) (affirming PTO determination that patent application did not contain sufficient written description even though it enabled persons skilled in the art to make and use invention).

The United States Patent and Trademark Office (PTO) itself has expressly recognized that "situations will arise" involving the Federal Circuit's separate written description requirement and the enablement requirement where "one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court." *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1101 (2001).

Indeed, by holding that its separate written description requirement invalidates petitioner's patent for failure to identify an implementing compound, Pet. App. 23a-24a, the Federal Circuit vividly demonstrates the impact of its additional requirement. By divorcing written description from enablement – and requiring a specific formula for a compound – the Federal Circuit has imposed a requirement that is not viewed through the lens of one skilled in the art, even where it is clear from the evidence introduced by petitioner that identification of an exact chemical formula was *not* required for persons skilled in the art to make and use petitioner's invention. This is dramatic, and not an inconsequential point as respondents attempt to make it.

b. Respondents also argue (Br. in Opp. 17-18) that because the separate written description and enablement requirements are two "distinct yet overlapping requirements,"

the court of appeals' failure to find that the enablement requirement was met means that the separate written description requirement is somehow not squarely presented in this case. But that, of course, begs the very question presented by this case. Under the correct interpretation of the statute there are not two distinct requirements; rather, the written description required is a description required "as to enable" and not for some separate judge-made purpose.

Respondents' view that it would be suitable for the Court to decide the question presented in a case only where the written description requirement is not satisfied but the enablement requirement is satisfied (Br. in Opp. 17-18), is inconsistent with notions of proper court decisionmaking whereby a court does not decide an issue that it does not have to. After all, if a court finds that a party loses on one ground (separate written description), a further holding that it would prevail on a second ground (enablement) is unnecessary to the judgment, and hence equivalent to dicta. The Federal Circuit ruled against petitioner on the ground that the patent failed to comply with the court's separate written description requirement, recognizing that, in so doing, it did not need to reach enablement. It would create perverse incentives if this judicial restraint became a reason not to grant *certiorari*.

B. Review Is Necessary To Eliminate The Disagreement In The Federal Circuit And The Resultant Uncertainty So As To Establish A Clear Rule To Govern The Application And Administrative Issuance Of Patents

1. Respondents attempt to bolster their argument that there is no disagreement or uncertainty on the question presented by claiming (Br. in Opp. 2, 9, 13-14, 20, 22) that the PTO "expressly endorse[s]" the Federal Circuit's interpretation of Section 112 to impose a separate written description apart from enablement. But the PTO has done no such thing.

First, the PTO's Guidelines, which respondents claim "confirm[]" the correctness of the decision below (Br. in

Opp. 9), were promulgated in furtherance of the PTO's duty to follow the law, including Federal Circuit precedent, *not* as an expression of the PTO's independent view that the Federal Circuit's interpretation of Section 112 is correct. *See* 66 Fed. Reg. at 1100 ("the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*"); *see also* 64 Fed. Reg. 71,427, 71,429 (1999) ("The [PTO] does not intend to impose a written description requirement that is more robust than that set forth by the courts.").

Second, respondents mischaracterize (Br. in Opp. 13-14) the United States' *amicus* brief on behalf of the PTO in support of rehearing *en banc* in *Enzo BioChem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002). The United States flatly asserted that "[a] straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." Brief of *Amicus Curiae* United States in *Enzo BioChem*, No. 01-1230 at 5 (filed July 2002), *available at* http://www.uspto.gov/web/offices/com/sol/ambriefs/Enzo.pdf (U.S. *Enzo BioChem amicus* brief); *id.* at 9 (same). It noted that the Federal Circuit had not adopted that straightforward reading and had "not rel[ied] on the text of the statute." *Ibid*; *see also id.* at 5-9 (discussing "at least three different possible Federal Circuit tests for an adequate 'written description'" in the course of urging *en banc* review to provide much needed guidance).

2. Respondents also claim that this Court has "indicated its agreement with the Federal Circuit on the question presented," quoting dicta in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), and citing an interpretation in *Evans v. Eaton*, 20 U.S. (7 Wheat) 356 (1822), of the Patent Act of 1793. Br. in Opp. 10. But *Festo*, in stating that an "application must describe, enable, and set forth the best mode," says nothing about the *relationship* between description and enablement, and thus cannot be read as expressing an opinion on the issue raised by this case. And the text of the 1793 Act specified a different role for the description, that was later eliminated by Congress and no longer exists in the current statute. *See* Pet. 20 (discussing interpretation

of Patent Act of 1793 in *Evans v. Eaton* and 1836 amendment).

3. a. Respondents' argument that *certiorari* should be denied because "there are no decisions" of the Federal Circuit "that are in conflict, or even in tension, with the holding in this case" is belied by the extensive discussion of such cases both by the dissenting judges below and the vast array of academic commentators who have analyzed the chaotic status of the Federal Circuit panel opinions on the issue. There is not an "unbroken line of cases spanning over thirty years uniformly affirming the existence of an independent written description requirement," as respondents claim. Br. in Opp. 11. The petition makes abundantly clear that the Federal Circuit's cases since 1967 are anything but uniform or consistent and have failed to provide adequate notice to patent applicants and examiners as to the source or meaning of a separate written description requirement untethered to the enablement standard of the statute. *See* Pet. 15-17.

Indeed, in the year prior to the instant case, two panel opinions affirmatively indicated that the separate written description standard of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998) (itself a dramatic departure from precedent that had not previously relied on the separate written description requirement to invalidate patents) did not extend to cases such as the instant one. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) (suggesting that the more demanding written description requirement of *Eli Lilly* was limited to "new or unknown biological materials"); *Moba v. Diamond Automation*, 325 F.3d 1306, 1320 (Fed. Cir.) ("In more recent cases . . . this court has distinguished *Lilly*."), *cert. denied*, 124 S. Ct. 464 (2003).

b. The inconsistent panel opinions of the Federal Circuit are as close as one will come to conflicting rulings because panels of the Federal Circuit are bound by prior three-judge panel decisions regardless of whether they agree with that panel's decision, unless the earlier panel is

reversed *en banc*. *See* Fed. Cir. R. 35(a)(2); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991).

This Court has reviewed numerous decisions of the Federal Circuit when a substantial number of its judges have raised significant questions about a legal rule adopted by the majority. *See, e.g., Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995) (reviewing Federal Circuit opinion in which suggestion for rehearing *en banc* was denied by a vote of six to five); *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83 (1993) (reviewing Federal Circuit opinion in which suggestions for rehearing *en banc* were denied over the dissents of three judges). The five dissenting votes from denial of rehearing *en banc* in this case should therefore weigh in favor of review. This is particularly so when one of the judges (Judge Newman) believes that Section 112 contains a separate written description requirement but nonetheless urged *en banc* review to quell the "continuing debate in panel opinions applying divergent law," Pet. App. 71a; and another (Judge Bryson) had joined the panel in *Eli Lilly*, supporting a separate written description requirement, but subsequently expressed doubts about whether the separate written description requirement is "based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1." Pet. App. 78a n.1; *Moba*, 325 F.3d at 1328 (Bryson, J., concurring).

4. Respondents' implication that the Court should deny review because "no other circuit has yet disagreed with the Federal Circuit" on its separate written description requirement ignores reality. As respondents note (Br. in Opp. 10), the other Circuit Courts of Appeals do retain limited appellate jurisdiction over cases that may involve patent law issues that are raised, for example, in counterclaims. But the number of appeals involving patent law heard by Circuits other than the Federal Circuit is so small as to be inconsequential. *See* Andrew G. Heinz, *Note: Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 84 B.U. L. Rev. 1103, 1130 n.224 (Oct. 2004) (since 2002, "over four hundred patent law cases have been heard by the Federal Circuit, while less than ten have been diverted to other jurisdictions"). Thus, no ruling by another Circuit on the question presented here (let alone a

ruling disagreeing with the Federal Circuit's interpretation to which other courts tend to defer on patent matters), is likely to ever occur, even though the Federal Circuit's ruling is contrary to the plain language of the statute.

C. The Federal Circuit's Interpretation Defies The Clear Statutory Text And Is Contrary To This Court's Plain Meaning Precedent

As the United States has previously declared, a "straightforward reading of the text of section 112" does not support the Federal Circuit's creation of a separate written description under Section 112 that is distinct from enablement. U.S. *Enzo BioChem Amicus* Br. 5. The petition demonstrates that the Federal Circuit's statutory interpretation is contrary to this Court's precedent instructing courts not to "read into the patent laws limitations and conditions which the legislature has not expressed." Pet. 18 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)).

Respondents contend that Section 112 requires a written description of two things – "of the invention" and "of the manner and process of making and using it." Br. in Opp. 18. Respondents ignore the statutorily required purpose of the written description of those two things, which must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112.

Respondents and the Federal Circuit disregard the grammar and syntax of Section 112 and read the statute as if the words "as to enable any person skilled in the art to which it pertains . . . to make and use the same" do not refer to the written description of the invention. But those words must refer to the written description of the invention because the final word "same" is a reference back to the earlier word "invention." The manner in which the commas are used in Section 112 further confirms this reading.

The problem is that the panels of the Federal Circuit have created a *separate* written description requirement distinct from the statutory requirement for a written

description that is in such terms as to enable. The Federal Circuit demands a written description that does more than enable. The judicially-created separate requirement has shifted over time. In this case, it was interpreted to require identification of a precise chemical compound, not just the method for treatment and the mechanism to identify a compound. By doing so, it went far beyond the enablement standard, which relies on what one skilled in the art can make and use based on the patent and which was supported by the uncontroverted expert evidence in the record. *See* Pet. App. 23a-24a. The ruling below jeopardizes all patents on methods by applying requirements found nowhere in the statutory text and should not be allowed to stand.

CONCLUSION

For the reasons set forth above and in the petition for a writ of *certiorari*, the petition should be granted.

Respectfully submitted,

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NOVEMBER 8, 2004